NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP1782 Transcutaneous electrical stimulation of the trigeminal nerve for ADHD**

Your information

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☒ I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. If consent is NOT given, please state reasons below:

Click here to enter text.

Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

Please note that questions 10 and 11 are applicable to the Medical Technologies Evaluation Programme (MTEP). We are requesting you to complete these sections as future guidance may also be produced under their work programme.

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology? Have you used it or are you currently using it? – Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake? – Is this procedure/technology performed/used by clinicians in specialities other than your own? – If your specialty is involved in patient selection or referral to another specialty for this	I have been familiar with eTNS procedure for at least 6 years. Initially, when covering for annual leave of my colleague, I met several patients who were already using this procedure for treatment of ADHD, I then had several patients who opted for the treatment with this procedure. I acted as a prescriber of the procedure for their treatment. I am not aware whether this procedure is used in NHS and I can not advise on the likely speed of uptake. The eTNS device is easy to set up and use, the procedure is self-administered by the patient at home and is well tolerated by most patients in my experience. The speed of uptake in NHS will be most likely influenced by the cost of the device. I am aware that in addition to the indication for ADHD, the procedure can be used in neurology for treatment of epilepsy. I have no contacts with neurologists who have experience in using this procedure for epilepsy. From my speciality perspective, it is useful to know that the procedure is not contraindicated in epilepsy, as in case of a psychiatric and neurological comorbidity this procedure offers a valuable alternative to the psychiatric medications which are often contraindicated in epilepsy or may worsen its symptoms.

	procedure/technology, please indicate your experience with it.	
2	– Please indicate your research experience relating to this procedure (please choose one or more if relevant):	~~I have done bibliographic research on this procedure.~~ ~~I have done research on this procedure in laboratory settings (e.g. device-related research).~~ ~~I have done clinical research on this procedure involving patients or healthy volunteers.~~ ~~I have published this research.~~ I have had no involvement in research on this procedure. - YES ~~Other (please comment)~~
3	How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design? Which of the following best describes the procedure (please choose one):	The eTNS procedure is a novel approach in treatment of ADHD compared to the current standard of care. The current standard of care includes pharmacology, psychological therapeutic modalities (CBT, coaching), psychosocial interventions and psychoeducation, environmental modification, dietary and lifestyle choices advice. The eTNS procedure is a neuromodulation-based non-invasive treatment intervention. Like medication, it develops its therapeutic effects through altering the function of the symptom's biological substrates, i.e. nerve cells in this context. Unlike medication though, eTNS achieves this not through a direct chemical effect of the nerve cell, but through stimulating the nerve cell with electrical current. ~~Established practice and no longer new.~~ ~~A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.~~

		~~Definitely novel and of uncertain safety and efficacy.~~ The first in a new class of procedure. -YES
4	Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?	For most adult patients, this procedure would be mainly used as an addition to the existing standard of care. For a smaller group of patients [this is for those who have absolute or relative contraindications for treatment with pharmacological methods] the procedure has a potential to replace the current standard. In addition, I think the procedure could potentially become a valid alternative for medication in the younger paediatric population as unlike the medication it is not associated with such side-effects as growth suppression.

Current management

5	Please describe the current standard of care that is used in the NHS.	I do not currently work in NHS. I understand that the current standard of care includes pharmacology, psychological therapeutic modalities (CBT, coaching), advice on environmental modifications, diet and lifestyle, psychosocial interventions and psychoeducation].
6	Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this? If so, how do these differ from the procedure/technology described in the briefing?	Transcranial direct current stimulation - tDCS – is the procedure which has somewhat similar mode of action to eTNS, but there are significant differences too. Both procedures use electrical current of a set amplitude Both procedures act through non-invasive neuromodulation Whilst eTNS is believed to stimulate trigeminal nerve, the tDCS stimulates cortex of the brain. eTNS is self-administered by the patient (or by their parent) at home, whilst tDCS is usually administered in a clinical setting (some more recent models with fixed settings can be also used at home) One eTNS procedure lasts 8 hours, one tDCS procedure for its usual indication [major depression] last approximately 20 min To my knowledge, unlike eTNS, the tDCS does not have a licenced indication for treatment of ADHD. There are numerous studies and a systematic review published on the effects of tDCS in

		ADHD. Positive effects are consistently reported but there is no consensus on the parameters of the tDCS procedure for ADHD, its duration, intensity etc.

Potential patient benefits and impact on the health system

7	What do you consider to be the potential benefits to patients from using this procedure/technology?	The potential benefit to the patients is their access to a neuromodulating treatment option other than medication. This is particularly relevant in the cases where medication is contraindicated, causes unacceptable side-effects or where monotherapy with medication is not effective enough.
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Yes. These groups include younger children who have not reached their full growth, patients with comorbid epilepsy, patients with other comorbidities where pharmacological treatment with stimulants or non-stimulants is contraindicated or causes severe side-effects.
9	Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system? Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?	The procedure is self-administered at home. Unlike with medication, where response to the treatment and side-effects must be monitored after each dose increase and the doses of the medication have to be adjusted accordingly, in case of eTNS there is no need for such frequent follow-up sessions during the treatment course. Standard pharmacological treatment with stimulants has a potential to cause dangerous side-effects, such as cardiovascular, neurological, and psychiatric side-effect, including tolerance and addiction to the drug, insomnia, mood destabilisation and even psychosis. The standard medication for ADHD has a potential for abuse. These risks do not apply to eTNS. This suggests that fewer visits to the hospital due to longer-term side-effects will be required. Patients self-administer the procedure at home, in the absence of a clinician. The schedule for reviews of the treatment effects is much less frequent than with medication. Baseline ECG is not required prior to starting eTNS.
10 - MTEP	Considering the care pathway as a whole, including initial capital and possible future costs avoided, is the procedure/technology likely to cost more or less than current standard care, or about the same? (in terms of staff, equipment, care setting etc)	I am unable to comment on this.
11 - MTEP	What do you consider to be the resource impact from adopting this procedure/technology (is it likely to cost more or less than standard care, or about	I am unable to comment on this.

	same-in terms of staff, equipment, and care setting)?	
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	The procedure is self-administered at home. I do not envisage any need to change the existing facilities to adopt eTNS.
13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Introductory training for the staff prescribing the procedure and monitoring its effects. Introductory training for the patient as to how to use the procedure delivering device at home.

Safety and efficacy of the procedure/technology

14	What are the potential harms of the procedure/technology? Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence: Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	eTNS has been reported to be generally well tolerated with no clinically meaningful adverse effects. Among its side-effects headache, dizziness, fatigue, clenching teeth, appetite increase, and sleep changes have been reported. 1. *McGough, J. (2019). Double-Blind Sham-Controlled, Pilot Study of Trigeminal Nerve Stimulation for ADHD. Am Acad Child Adolesc Psychiatry 2019 Apr;58(4):403-411.* 2. *McGough, J. (2014). An Eight-Week, Open-trial, Pilot Feasibility Study of Trigeminal Nerve Stimulation in Youth With Attention-deficit/Hyperactivity Disorder. Brain Stimulation November 2014 DOI:https://doi.org/10.1016/j.brs.2014.11.013* In my own experience, a sleep disturbance has been reported to me onlyt once. One patient was unable to use the procedure because it was inducing nasal congestion. Interestingly, most patients usually report improvement in sleep when receiving the procedure. The main challenge for my patients has been the compliance with regular treatment procedures. Some of the patients would find it too demanding to use the device on a daily basis for 8 hours a day for 8 weeks, and they struggle with creating a regular routine for self-administering the procedure. On the other hand, many patients would rather prefer this treatment mode to the medication. " "

15	Please list the key efficacy outcomes for this procedure/technology?	Reduction in ADHD Rating Scores and GCI-I, with NNT (based on GCI) =3 at week 4 *Mc Gough, J. (2019). Double-Blind Sham-Controlled, Pilot Study of Trigeminal Nerve Stimulation for ADHD. Am Acad Child Adolesc Psychiatry 2019 Apr;58(4):403-411.*
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	It is not yet clear as to how durable the effects of the treatment are after discontinuation of the treatment. For that reason, there is yet no established practice for most effective schedule of maintenance procedures. Currently, the maintenance schedule is individually tailored for each patient based on their subjective experience of sustainability of the therapeutic effects on completion of the acute (i.e. 8 weeks of daily sessions) treatment course. I do not have safety concerns at this point.
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	I do not have any concerns of this kind.
18	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	~~Most or all district general hospitals.~~ A minority of hospitals, but at least 10 in the UK. ~~Fewer than 10 specialist centres in the UK.~~ ~~Cannot predict at present.~~

Abstracts and ongoing studies

19	Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work). Please note that NICE will do a comprehensive literature search; we are	I have no items to list.

	only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.	
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	My understanding is that Professor Katya Rubia at King's College London is starting a comprehensive clinical research on eTNS use in paediatric population, funded by NIHR.

Other considerations

21	Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?	I do not work in NHS and I am unable to provide an expert opinion on this matter. Given that the procedure is well tolerated and is contraindicated in only very rare circumstances, it has a certain advantage over standard pharmacological treatments in terms of burden of side-effects. For this reason, I believe that if the procedure was offered to each patient in need of treatment for ADHD, as an alternative to medication, it is likely that in the pediatric polulation most parents/carers would prefer this non-invasive neuromodulation-based procedure over the pharmacological treatment options. The volume of the people eligible for this procedure per year will therefore rather depend on the capacity of promptly diagnosing the patients and will be proportionate to the number of people being assessed and diagnosed with this conition. In terms of the adult population, it is my experience that at least a third of my patients with ADHD have psychiatric or physical comorbidities making the use of the medication complicated or potentially unsafe. Such group of patients would likely prefer to utilise the option of eTNS prior to considering medication.
22	Are there any issues with the usability or practical aspects of the procedure/technology?	The electrodes for eTNS device are disposable and their supply needs to be regularly replenished. Whilst asleep, patients often toss around and disconnect electrodes from the device without being aware of it. The device then automatically goes in the error mode. By morning it is impossible to say how many hours the device had been working for at night, whether it got disconnected 20 minutes after starting the procedure or whether it worked for almost the whole duration of the procedure.

		Compliance is a challenge for many adult patients whose ability to self-organise and follow routines is already affected by their ADHD. Some patients may start the treatment course but do not have enough patience to wait till it starts developing its therapeutic effects. They disengage from eTNS and opt for switching to medication.
23	Are you aware of any issues which would prevent (or have prevented) this procedure/technology being adopted in your organisation or across the wider NHS?	The cost of the equipment. The procedure is not in NICE guidelines.
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	Longitudinal studies on durability of the clinical effects, best maintenance practices.
25	Please suggest potential audit criteria for this procedure/technology. If known, please describe: − Beneficial outcome measures. These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured. − Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:	***Beneficial outcome measures:*** I am unable to comment on the paediatric population. For an audit in a clinical setting for adult patients, I suggest the following scales/inventories to be completed at baseline, and then on week 4 of the treatment, on week 8 of the treatment, and week 4 after completion of the 8-weeks' course of treatment : 1. Adult ADHD Self-Report Scale (ASRS-v1.1) Symptom Checklist 2. Weiss Functional Impairment Rating Scale Self-Report 3. The Clinical Global Impressions Scale The tools listed below can be used in addition to the above: 4. Brown ADD scale 5. Self-Report Adult ADHD Symptoms and Role Impairment Inventory 6. Clinician Adult ADHD Symptom and Role Impairment Inventory 7. Third Party Adult ADHD Symptoms and Role Impairment Inventory ***Adverse outcome measures:*** I am unable to comment on the paediatric population. For auditing adverse effects in adult population, a checklist of the already documented side-effects of eTNS could be created with an option "other" if any non-listed side-effects emerge. Alternatively, Medication Treatment Emergent Effects Checklist could be utilised. The checklist

		would need to be filled in at baseline, and then within an hour on completion of the treatment session 1, then on week 4 of the treatment, on week 8 of the treatment, and week 4 after completion of the 8-weeks' course of treatment.
26	Is there any other data (published or otherwise) that you would like to share with the committee?	No

Further comments

26	Please add any further comments on your particular experiences or knowledge of the procedure/technology,	My experience with eTNS is not vast, but probably enough to form some impressions based on the clinical practice. In my experience most adults achieve an improvement in their symptoms, and some of them achieve a full remission with eTNS monotherapy. I have come across cases where it was possible to fully avoid use of the medication due to using eTNS. The main challenge for adults is consistent compliance with the treatment, particularly on completion of the 8 weeks' treatment course, after switching to maintenance schedule. The latter is individually agreed in each case and varies from once a week to once a month. Adult patients may find it inconvenient that the treatment session lasts 8 hours – they do not like wearing the electrodes on their forehead and the device attached to their clothes during their sleep time, particularly if they are in a new relationship and share bed with a new partner. With their busy schedules during the day, the adult patients are often unable to secure an eight-hour uninterrupted session of the treatment during their awake time. It is my observation that though eTNS offers a safe and effective alternative to medication, only highly motivated adults will be able to comply with the whole course of the treatment. It is not a suitable alternative for the category of the patients whose symptoms manifest as particularly heightened impulsivity and inability to self-organise.

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Declarations of interests

Please state any potential conflicts of interest relevant to the procedure/technology (or competitor technologies) on which you are providing advice, or any involvements in disputes or complaints, in the previous **12 months** or likely to exist in the future. Please use the NICE policy on declaring and managing interests as a guide when declaring any interests. Further advice can be obtained from the NICE team.

Type of interest *	Description of interest	Relevant dates	
		Interest arose	Interest ceased
Choose an item.			
Choose an item.			
Choose an item.			

☒ I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

Please note, all declarations of interest will be made publicly available on the NICE website.

Print name:	**Irina Panihhidina**
Dated:	**02/06/2022**

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Professional Expert Questionnaire

Technology/Procedure name & indication: **IP1782 Transcutaneous electrical stimulation of the trigeminal nerve for ADHD**

Your information

Name:	Click here to enter text. Mohamed Abdelghani
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Professional organisation or society membership/affiliation:	Click here to enter text. GMC / RCPsych
Nominated/ratified by (if applicable):	Click here to enter text. RCPsych
Registration number (e.g. GMC, NMC, HCPC)	Click here to enter text. GMC: 6112160

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Click here to enter text.

Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

Please note that questions 10 and 11 are applicable to the Medical Technologies Evaluation Programme (MTEP). We are requesting you to complete these sections as future guidance may also be produced under their work programme.

1	Please describe your level of experience with the procedure/technology, for example:	
	Are you familiar with the procedure/technology?	Yes.
	Have you used it or are you currently using it?	I have expertise in neuromodulation treatments and I have used Trigeminal Nerve Stimulation (TNS) in clinical settings.
	− Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake?	I'm not aware that TNS is currently being used in the NHS. The likely speed of uptake by the NHS should be quick.
	− Is this procedure/technology performed/used by clinicians in specialities other than your own?	Yes, neurology.
	− If your specialty is involved in patient selection or referral to another specialty for this	No

	procedure/technology, please indicate your experience with it.	
2	− Please indicate your research experience relating to this procedure (please choose one or more if relevant):	I have had no involvement in research on this procedure. Other (please comment)
3	How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design? Which of the following best describes the procedure (please choose one):	TNS for the treatment of ADHD is quite innovative as the other treatments available and recommended in the UK only includes medications (such as stimulant medications) and psychological therapies (talking therapy). The first in a new class of procedure.
4	Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?	TNS could be used as an adjunct treatment for ADHD. However, it could also be used as a stand-alone treatment for patient who cannot or does not want medication to treat their ADHD.

Current management

5	Please describe the current standard of care that is used in the NHS.	For ADHD: - Environmental adjustment - Medications - Psychological Therapy.

6	Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this? If so, how do these differ from the procedure/technology described in the briefing?	No

Potential patient benefits and impact on the health system

7	What do you consider to be the potential benefits to patients from using this procedure/technology?	Being able to treat / manage ADHD symptoms using a medication free treatment modality.
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Yes, patients who cannot take ADHD medications because of cardiac problems. Patients who cannot take ADHD medications because of severe side effects.
9	Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system? Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?	Yes, for all what is mentioned.
10 - MTEP	Considering the care pathway as a whole, including initial capital and possible future costs avoided, is the procedure/technology likely to cost more or less than current standard care, or about the same? (in terms of staff, equipment, care setting etc)	I'm not certain about the cost of a TNS device and the patches that has to be applied on the patient's forehead but I believe it could more expensive that ADHD medication.
11 - MTEP	What do you consider to be the resource impact from adopting this procedure/technology (is it likely to cost more or less than standard care, or about same-in terms of staff, equipment, and care setting)?	I'm not certain about the cost of a TNS device and the patches that has to be applied on the patient's forehead but I believe it could more expensive that ADHD medication.
12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	eTNS is a hand-held device, thus no changes are needed for existing facilities.

13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Yes, however this can be done in a short period of time (around half an hour).

Safety and efficacy of the procedure/technology

14	What are the potential harms of the procedure/technology? Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence: Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	Tingling, pain and discomfort at the site of stimulation. Skin irritation Headache
15	Please list the key efficacy outcomes for this procedure/technology?	
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	
18	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	Most or all district general hospitals. A minority of hospitals, but at least 10 in the UK. Fewer than 10 specialist centres in the UK.

		Cannot predict at present.

Abstracts and ongoing studies

19	Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work). Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.	https://pubmed.ncbi.nlm.nih.gov/30768393/ https://pubmed.ncbi.nlm.nih.gov/33068751/ https://pubmed.ncbi.nlm.nih.gov/25533244/
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	

Other considerations

21	Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?	I estimate that out of the patients diagnosed and receiving treatment for ADHD around 10% might be eligible for this intervention.
22	Are there any issues with the usability or practical aspects of the procedure/technology?	No major issues with usability or practical aspects.

23	Are you aware of any issues which would prevent (or have prevented) this procedure/technology being adopted in your organisation or across the wider NHS?	No
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	
25	Please suggest potential audit criteria for this procedure/technology. If known, please describe: − Beneficial outcome measures. These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured. − Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:	Beneficial outcome measures: Adverse outcome measures:
26	Is there any other data (published or otherwise) that you would like to share with the committee?	https://pubmed.ncbi.nlm.nih.gov/30768393/ https://pubmed.ncbi.nlm.nih.gov/33068751/ https://pubmed.ncbi.nlm.nih.gov/25533244/

Further comments

26	Please add any further comments on your particular experiences or knowledge of the procedure/technology,	

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Type of interest *	Description of interest **Please note that the link above is not working. When I clicked on it I got a message saying "We can't find this page. It's probably been moved, updated or deleted"**	Relevant dates	
		Interest arose	Interest ceased
Direct - financial	In my private practice, TNS is one of the treatment modalities we offer to our patients.		
Choose an item.			
Choose an item.			

☒ I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

Please note, all declarations of interest will be made publicly available on the NICE website.

Print name:	**Click here to enter text.Dr Mohamed Abdelghani**
Dated:	**Click here to enter text. 24.05.2022**